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Editorial Comment

Is Reuse of Coronary Angioplasty Catheters Safe and Effective?*

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There has been a tremendous increase in the use of coronary angioplasty for the treatment of ischemic heart disease during the past 10 years. It is estimated that in 1993 >400,000 coronary angioplasty procedures were performed in the United States and ~800,000 worldwide (1). This rate of intervention and, therefore, the cost of equipment and personnel involved in this technology are not expected to stabilize or decrease in the foreseeable future. These escalating costs place a considerable burden on the health care systems of developed countries. To alleviate this burden, several North American and European cardiovascular centers have adopted the policy of reusing cardiac and, especially, angioplasty balloon catheters that are sold in packages marked for single use only (2,3). The extent of this practice has been highlighted in recent surveys. A report (4) from the Institute of Health Policy Analysis in the United States in 1986 revealed that 31% of the responding hospitals reused cardiac catheters and that among the so-called disposable medical devices they were the most reused item after hemodialysis filters. A report (5) from the Canadian Coordinating Office for Health Technology Assessment in 1991 showed that 39% of cardiovascular centers in Canada, including nearly all centers in Quebec, reused cardiac and coronary angioplasty catheters. Unfortunately, however, not all Canadian hospitals had a formal written catheter reutilization policy and procedures to ensure the safety and effectiveness of interventions performed with reused catheters.

In this issue of the Journal, Plante et al. (1) compare the experiences of two Canadian centers performing coronary angioplasty over a 10-month period, one of them using new angioplasty balloon catheters only and the other using both new and reused catheters. Compared with the single-use center, the center reusing catheters had a cost saving per lesion of $274, and an overall saving of ~$110,000 (Canadian dollars) over the course of the study. However, the reuse center experienced more technical problems (i.e., more catheters used per lesion, a higher incidence of failure to cross the lesion initially, longer procedures and an increased volume of contrast material per procedure). The reuse center also experienced a higher incidence of abrupt closure and adverse clinical events (i.e. procedure-related death, myocardial infarction and urgent coronary artery bypass grafting). Plante et al. suggest that it was the strategy of angioplasty balloon catheter reuse that was associated with these technical problems and with the higher rate of adverse clinical events.

Limitations of this study. The resterilization and reuse of angioplasty balloon catheters has been performed routinely in many cardiovascular centers for several years, and the experience accumulated thus far indicates that this practice is as safe and clinically effective as using only new angioplasty catheters. However, the current study is probably the first report to address this issue in a structured manner. Therefore, the limitations of this observational study must be clearly emphasized, because if its conclusions were to be accepted without challenge, all hospitals that are now reusing catheters should consider immediately abandoning such a policy and foregoing the cost savings that they now generate. For example, the Province of Quebec is nearly completely converted to diagnostic and angioplasty catheter reuse, and this policy generates ~$6,500,000 (Canadian dollars)/year (2). If this practice was discontinued, comparable budgetary cuts would have to be made in other essential health services.

Obviously, as Plante et al. fully acknowledge, only a carefully planned and performed, preferably multicenter, randomized trial could determine whether their results can really be attributed to catheter reuse or to other practice patterns within each center, particularly the experience and skill of the operators who were involved with these procedures.

First, we do not know how many operators were performing angioplasty procedures at each center during the period of the study and how many procedures each performed per week or per month. We know that both centers are small- or medium-volume centers, performing <1.5 procedures/day. Not all operators in a given center have the same experience and skill. Therefore, it is possible that the higher incidence of technical problems and, consequently, of adverse clinical events at the reuse center were related to the lesser experience or performance of one or two operators. This, of course, could be clarified by looking at the results of each operator involved in the study.

With regard to patient selection, the higher incidence of patients with unstable angina at the reuse center accounted at least in part for the difference in the results between the two centers. The results were similar in patients with stable coronary artery disease. In addition to being small- or medium-volume angioplasty centers, both centers were performing mainly single-vessel angioplasty, even in patients with multivessel coronary artery disease. Only 7% to 8% of their procedures involved more than one vessel. This may not be representative of the practice of most large academic centers in North America today.

The mean number of balloon catheters used at the reuse center was 5.2, and some catheters were used up to 13 times. This largely exceeds the recommendation of the Council of

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Health Technologies in Quebec which states that, regardless of physical appearance, an angioplasty catheter should not be used more than three times (2,3). Moreover, Figure 1 of the Plante et al. study clearly shows that little is gained financially after more than two reuses. It would be interesting to see what results would be obtained if this rule was followed.

Besides clinical safety and efficacy, there are other potential risks to catheter reuse that are not specifically addressed by Plante et al., including infections, pyrogenic reactions, toxicity, particulate contamination, catheter breakage and biologic incompatibility (2,3). These risks exist even when new equipment is used. Surveys show that centers reusing catheters also resterilize those that have not been used (4). The aforementioned risks have been assessed, and the results of these studies show that when standardized procedures of cleaning, sterilization and quality control are followed, undamaged reused catheters are as safe as new catheters (2,3).

The practice of reuse may lead to a slight increase in the number of catheters used during coronary angioplasty and to some increase in procedure time because a catheter will occasionally have to be replaced.

Reuse of catheters results in moderate savings, as shown by Plante et al. This finding may be very important in an era of cost restrictions and containment. Moreover, the money saved in this way can be used to achieve other goals and priorities. However, this practice cannot be ethically and legally defendable unless the users can prove that it is not more harmful and does not give less adequate results than the use of new catheters only.

Finally, two recommendations can be made at present. First, hospitals that reuse coronary angioplasty catheters must have a clear policy concerning catheter sterilization that is never concealed, and it is mandatory that they have standardized procedures for the cleaning, sterilization and quality control of reused catheters, similar to those described by Plante et al. Second, randomized clinical trials are sorely needed to assess in a more definitive fashion the safety and efficacy of catheter reuse in a format setting.

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